

# Use of extraglottic airways in patients undergoing ambulatory laparoscopic surgery without the need for tracheal intubation

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## ABSTRACT

**Background:** Second generation extraglottic airway devices with gastric access and separate breathing channels have ushered in a new era where their use is increasingly prevalent in surgical patients who would have been traditionally intubated for general anesthesia. New innovations like the i-gel, which is constructed of a thermoplastic elastomer, provide an airtight seal around patient's perilaryngeal anatomy without the inflatable cuff mechanism found in the laryngeal mask airway supreme (LMAS). **Methods:** We conducted a randomized controlled trial comparing the LMAS with the i-gel in 70 anesthetized paralyzed patients undergoing laparoscopic female sterilization. Our primary outcome measure was the oropharyngeal leak pressure (OLP). We studied secondary outcomes of successful first attempt insertion rates, time and ease of the airway and gastric tube insertion, leak fractions and pharyngeal morbidity. **Results:** We found no difference in the OLP between LMAS and i-gel, 25.9 (4.2) versus 24.4 (4.3) s,  $P=0.153$ . Both devices had similar first attempt insertion rates (LMAS 94% vs. i-gel 91%) with similar ease and comparable times to achieve an effective airway, LMAS 14.7 (2.7) versus i-gel 16.5 (9.6) s,  $P=0.306$ , although gastric tube insertion was easier and faster for the LMAS, 7.9 (1.9) versus i-gel 14.8 (7.7) s,  $P<0.005$ . Intraoperatively, there was a significantly greater leak fraction with the i-gel of 0.06 (0.03) versus 0.04 (0.02) with the LMAS,  $P=0.013$ . Three patients (8.6%) with LMAS had mild sore throat; one patient (2.9%) had mucosal injury. No complications were documented in the i-gel group. **Conclusions:** Both these extraglottic airway devices offer similar OLPs, high insertion success rates at the first attempt with similar ease and insertion times (albeit longer gastric tube insertion with i-gel). Both provided effective ventilation despite a higher leak fraction with i-gel that was clinically inconsequential.

**Key words:** *Extraglottic airway devices, i-gel, laparoscopic surgery, laryngeal mask airway supreme, leak fraction, leak pressures*

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## INTRODUCTION

Archie Brain has revolutionized airway management since the 1980s with his original laryngeal mask invention.<sup>[1]</sup> Introduction of the second generation extraglottic airway devices with a gastric drain port and separate breathing channel then heralded a new era where these devices are now widely used for surgery in patients who would have

been traditionally intubated for general anesthesia and in out-of-hospital settings, where less experienced personnel such as paramedics and emergency physicians have to secure the airway.<sup>[2]</sup>

Previously, the reusable ProSeal laryngeal mask airway (LMA) was shown to be a similarly effective airway device to conventional laryngoscope-guided tracheal intubation in laparoscopic gynecological procedures, with more rapid insertion and attenuated hemodynamic response to insertion and removal.<sup>[3]</sup>

Subsequently, the disposable LMA Supreme™ (LMAS™) (LMAS™; Laryngeal Mask Company, Singapore) was introduced and its use became prevalent in ambulatory surgical centers. It comprises a single-use, latex-free, LMA with an anatomically shaped semi-rigid airway tube, gastric

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access port that admits an orogastric tube and a built in bite block.

The i-gel™ (Intersurgical Ltd, Wokingham, Berkshire, United Kingdom) was invented by Muhammed Aslam Nasir. It is a novel single-use, latex free extraglottic airway device that differs from the LMAS as it does not have an inflatable cuff. The rim of the mask is designed to conform to the anatomical shape of the larynx. This enables the device to provide an airtight seal without the cuff mechanism. It is uniquely constructed of a thermoplastic elastomer (styrene ethylene butadiene styrene) that is soft, transparent and malleable, changing its form based on each patient's laryngeal anatomy.<sup>[4]</sup> The tube consists of two channels, where it is possible to intubate the trachea through the breathing tube and to insert a gastric tube through the drain tube. Preliminary studies point to easy insertion, less tissue compression and adequate sealing pressures.<sup>[5,6]</sup>

In non-paralyzed patients, Gatward's *et al.*<sup>[6]</sup> and Díez *et al.*<sup>[7]</sup> success rate for i-gel insertion on the first attempt was 86%, whereas the LMAS was associated with 95% success. We postulated that this difference would be mitigated by neuromuscular blockade and tested the hypothesis that there would be no difference in the first attempt insertion rates between the two devices in a non-obese population of non-difficult airways undergoing female laparoscopic sterilization in our ambulatory surgical center, where an average of 460 cases were performed annually from 2007 to 2009 (unpublished hospital data).

Considering the differences in the anatomy of cuffs of the novel i-gel extraglottic device devoid of inflatable cuff, sample size calculation was powered to the oropharyngeal leak pressures (OLP) as a primary endpoint. We studied secondary outcomes of successful first attempt insertion rates, time to insertion and ease of insertion of airway device and gastric tubes, efficacy with controlled positive pressure ventilation and pharyngeal morbidity.

## METHODS

Institutional review board approval was obtained and all patients gave their written informed consent. We recruited 70 American Society of Anesthesiologists (ASA) physical Status I-II non-obese women without predictors of difficult airway who underwent laparoscopic sterilization with neuromuscular blockade and controlled ventilation as a day case procedures. Patients with ASA physical Status III or IV, body mass index >35 kg/m,<sup>[2]</sup> suspicion of difficult airway, with symptoms of gastroesophageal reflux and heartburn were excluded.

Patients were randomized into two groups: LMAS or 'i-gel'; using a computer generated random number table. After recruitment, the enrolling investigators opened sealed opaque envelopes that concealed group allocation. Participants were blinded to their group allocation. Size of the extraglottic airway device was guided by manufacturer's recommendation, but with investigator preference for choosing the largest size LMA that could accommodate the patient's mouth opening to obtain good seal pressures. Both investigators had experience with more than 300 LMA insertions.

Patients were positioned on the operating table with their heads resting on a jelly doughnut. Standard monitoring was applied and patients were preoxygenated until end tidal oxygen >0.80 before induction of anesthesia with fentanyl 1-2 mcg/kg and propofol 2-3 mg/kg. Mivacurium 0.2 mg/kg was given after confirming the adequacy of manual ventilation. The extraglottic airway device was then inserted after adequate jaw relaxation within 1-2 min.

Both extraglottic devices were prepared and lubricated with a water based lubricant as per manufacturer's recommendations. Successful insertion rates on first and second attempts, time to insertion (the interval between LMA entering the mouth to first end-tidal carbon dioxide (ETCO<sub>2</sub>) trace on the monitor) and the ease of airway insertion (on a graded scale, where 1-easy, 3-difficult, 5-impossible) was recorded. Any maneuvers required to optimize the positioning or ventilation with the airway devices, such as adjusting patient's head or neck position, adjusting the depth of insertion, applying jaw lift and changing device size were also recorded. The appearance of the first square ETCO<sub>2</sub> trace denoted successful establishment of effective ventilation. Otherwise, the device was completely removed for another insertion attempt. Three attempts at insertion were allowed. Each attempt was performed with complete removal of the airway from the mouth and reinsertion. Insertion failure was declared if 3 unsuccessful attempts were encountered or if the entire process of insertion exceeded 120 s. In case of failure of insertion, the airway was secured according to the decision of the attending consultant anesthetist.

The volume of air in the cuff required to obtain 60 cm H<sub>2</sub>O pressure for the LMAS was also noted. A gel plug was then placed in the proximal 1 cm of the gastric drain outlet and tapping on the suprasternal notch elucidated a gentle oscillation of the gel plug as a confirmatory test that the tip's location was in continuity with the upper esophageal sphincter. A 14 F gauge gastric tube for LMAS and 12 F gauges for the i-gel were inserted through the gastric channel and the ease of insertion and time to insertion were noted. Placement was confirmed by positive gastric

aspiration or detection of injected air while auscultating the epigastrium. Decompression of patient's stomach was then done and the gastric tube was allowed to drain freely during surgery.

The OLP was measured after closing off the adjustable pressure limiting valve, with a fresh gas flow of 3l/min in the circuit, noting the airway pressure achieved at equilibrium on the airway pressure manometer or when there was an audible "gurgling" sound denoting an air leak from the throat. This pressure was not allowed to exceed 40 cm H<sub>2</sub>O.

Anesthesia was maintained with sevoflurane 1-2 minimum alveolar concentration in an oxygen/air mixture. The attending anesthetist was free to adjust the ventilator to achieve effective ventilation using volume controlled, intermittent positive pressure ventilation. The aim was to achieve SpO<sub>2</sub> ≥ 95% and end-tidal CO<sub>2</sub> of 35-45 mmHg through tidal volumes of 8-10 ml/kg and respiratory rate of 10-16/min. The difference between inspired and expired tidal volume was calculated to give the leak volume. The leak fraction was defined as the leak volume divided by the inspired tidal volume. Airway pressure before and after creation of pneumoperitoneum and intra-abdominal pressure during surgery were documented. Intravenous ketorolac 30 mg (Hospira, Inc Lake Forest, IL, USA) or tramadol 50 mg (DuoPharma (M), Selangor, Malaysia) (for those with an allergy to non-steroidal anti-inflammatory drugs) was administered for post-operative pain relief. The duration of surgery was also recorded.

Neuromuscular blockade was antagonized with atropine 0.02 mg/kg and neostigmine 0.04 mg/kg. The extraglottic airway device was removed once patient had spontaneous breathing, return of airway reflexes and eye opening. The airway device was then inspected for the presence of visible blood on the surface. Patients were interviewed 45 min later in the recovery unit by a blinded independent observer for sore throat, dysphonia or dysphagia.

### Statistical analysis

The sample size was based on our primary outcome measure of OLP. From a previous study comparing extraglottic airway efficacy against tracheal intubation for gynecological laparoscopy, the mean (standard deviation (SD)) OLP of the LMA was 27 (4) cm H<sub>2</sub>O.<sup>[3]</sup> We deemed 10% to be a clinically significant difference between our two extraglottic airway devices to be tested. Prospective power analysis indicated that with  $\alpha=0.05$  and power of 80%, 32 patients per group were needed. Therefore, we recruited 35 patients per group to account for dropouts. Parametric data and non-parametric data was analyzed with Student's *t*-test and Mann-Whitney *U* test respectively and Fisher's exact test was used to compare side-effects

using Statistical Package for the Social Sciences (SPSS) 16.0™ (SPSS Inc., Chicago, IL, USA) software. A  $P<0.05$  was deemed statistically significant.

## RESULTS

In each airway device group, 35 patients were recruited, completed the study and were analyzed. The baseline demographics and pre-operative airway characteristics of patients in both groups were comparable, except that by chance the patients that underwent laparoscopic sterilizations in the i-gel group were found to have fasted an hour more than those in the LMA group [Table 1].

We found no significant difference in the OLP between the two airway device groups [Table 2]. 94% LMA and 91% i-gel were successfully placed on the first attempt,

**Table 1: Baseline demographics of patients randomized to LMA supreme and i-gel, expressed as mean (SD) or number (%)**

Demographic variable	LMA supreme (n=35)	i-gel (n=35)	P value
Age (years)	35.3 (4.8)	33.0 (5.1)	0.059
Height (m)	156.5 (6.3)	157.9 (5.7)	0.355
Weight (kg)	59.0 (10.6)	63.5 (16.8)	0.194
BMI (kg/m <sup>2</sup> )	24.0 (4.1)	25.3 (5.9)	0.309
Fasting hours (h)	12.2 (3.1)	13.6 (2.6)	0.050
Duration of surgery (min)	33.1 (9.7)	36.0 (7.2)	0.160
ASA			
1	29 (82.9)	25 (71.4)	0.258
2	6 (17.1)	10 (28.6)	
Mallampati			
1	12 (34.3)	12 (34.3)	0.559
2	18 (51.4)	14 (40.0)	
3	5 (35.7)	9 (25.7)	
Thyromental distance			
<6.5 cm	33 (94.3)	30 (85.7)	0.235
>6.5 cm	2 (5.7)	5 (14.3)	
Sternomental distance			
<12.5 cm	1 (2.9)	2 (5.7)	0.558
>12.5 cm	34 (97.1)	33 (94.3)	
Interincisor distance			
<4 cm	7 (20)	7 (20)	1.000
>4 cm	28 (80)	28 (80)	
Ability to prognath			
Yes	33 (94.3)	31 (88.6)	0.397
No	2 (5.7)	4 (11.4)	
Head/neck movement			
Normal>90°	35 (100)	35 (100)	1.000
Abnormal<90°	0 (0)	0 (0)	

SD – Standard deviation; LMA – Laryngeal mask airway; BMI – Body mass index; ASA – American society of anesthesiologists

**Table 2: Leak volumes, pressures and airway insertion characteristics. Values are mean (SD) or actual number (%)**

Parameter assessed	LMA supreme (n=35)	I-gel (n=35)	P value
Oropharyngeal leak pressure, cm H <sub>2</sub> O	25.9 (4.2)	24.4 (4.3)	0.153
Size of airway used: 3/4/5	7/28/0	14/18/3	0.367
Number of insertion attempts (%)			
1	33 (94.3)	32 (91.4)	0.645
2	2 (5.7)	3 (8.6)	
3	0	0	
Time to successful airway insertion (s) <sup>†</sup>	14.7 (2.7)	16.5 (9.6)	0.306
Reported ease of insertion			
1=Easy	31 (88.6)	31 (88.6)	1.000
2=Not so easy	4 (11.4)	4 (11.4)	
3=Difficult	0	0	
4=Very difficult	0	0	
5=Impossible	0	0	
Cuff volume at 60 cm H <sub>2</sub> O	23.2 (3.8)	NA	
Time to gastric tube insertion (s)*	7.9 (1.9)	14.8 (7.7)	<0.001
Ease of gastric tube insertion			
1=Easy	35 (100)	27 (77.1)	0.005
2=Difficult	0	8 (22.9)	
3=Impossible	0	0	
Airway pressure post-pneumoperitoneum (cm H <sub>2</sub> O)	23.3 (6.3)	22.8 (4.4)	0.663
Intra-abdominal pressure (mmHg)	14.1 (2.5)	15.2 (2.4)	0.07
Max inspired tidal volume (ml)	438.0 (52.5)	481.7 (84.6)	0.012
Expired tidal volume (ml)	422.0 (50.9)	464.3 (82.9)	0.013
Leak volume (ml)	18.46 (9.6)	28.63 (18.1)	0.005
Leak fraction	0.042 (0.02)	0.059 (0.03)	0.013

<sup>†</sup>Defined as time from insertion of airway device into patient's mouth to the first end-tidal carbon dioxide trace; \*Defined as time from gastric tube first entering gastric drainage channel to 64 cm depth of insertion. SD Standard deviation, LMA – Laryngeal mask airway; NA – Not available

with similar ease and comparable times to successfully achieve an effective airway. Two LMAS and three i-gels were successfully placed on the second attempt. There were no cases of failed insertion of either airway device. Nearly, 88.6% of both LMAS and i-gel insertions were easy, 11.4% not so easy, none were deemed difficult, moderately difficult or impossible to insert on the subjective graded scale used to assess the ease of insertion.

Time to successful insertion of the airway devices did not differ significantly, but insertion of gastric tube for i-gel group took longer and was more difficult than for the LMAS [Table 2]. 33 LMAS and 32 i-gels did not require any maneuvers to be effective ventilatory devices however, two LMAS<sup>TM</sup> and three i-gels were reinserted to achieve optimal ventilation. The mean (SD) volume of air needed to achieve a cuff pressure of 60 cm H<sub>2</sub>O was 23.2 (3.8) in the LMAS. Intra-abdominal pressure and airway pressure after creation of pneumoperitoneum were comparable among the two airway groups, but there was a significantly higher leak volume and leak fraction with the i-gel [Table 2].

Data on post-operative complications revealed no significant differences. Three patients (8.6%) in the

LMAS group complained of mild sore throat and one patient (2.9%) had mucosal injury (blood on the surface of airway on removal), but no post-operative complications were documented in the i-gel group. Nobody in the 2 study groups experienced desaturation, gross regurgitation, lip injury, dysphagia, dysphonia or dental injury.

## DISCUSSION

We found the LMAS<sup>TM</sup> and i-gel were both inserted equally quickly, easily and had high rates of successful first attempt insertion of 94% and 91% respectively. It was more difficult and took longer to insert the gastric tube for i-gel due to its small gauge gastric access port compared with LMAS. There were no differences in the OLPs between the 2 devices, but the i-gel had a higher leak fraction (leak volume divided by the inspired tidal volume) of 0.06 versus LMAS 0.04. Despite this statistically significant greater air leak difference, its performance was not affected clinically as we found comparable oxygenation, ventilation and delivery of anesthetic gases throughout surgery without any difficulty.

Indeed, Uppal *et al.*<sup>[8]</sup> had previously proven that the i-gel was an acceptable alternative to tracheal intubation during pressure controlled ventilation using moderate airway pressures up to 25 cm H<sub>2</sub>O, with no significant gas leak. After induction of pneumoperitoneum for the laparoscopic sterilization procedures, the mean airway pressures in our patients were only 23 cm H<sub>2</sub>O, well within this previously investigated limit.

In sixty patients who underwent laparoscopic cholecystectomy under general anesthesia with positive pressure ventilation, the i-gel was found to be as good as intubation with a tracheal tube. There was no difference in leak volume, leak fraction and airway pressure between the two groups.<sup>[9]</sup> These trials lend further evidence to the fact that tracheal intubation can be substituted with efficient extraglottic airway management in selected patients and types of surgery.

Gatward *et al.*<sup>[6]</sup> demonstrated reliability, rapid and easy insertion of size 4 i-gel in a hundred non-paralyzed patients with median insertion time of 15 s and OLP of 24 cm H<sub>2</sub>O, which was comparable with our findings. However, their successful first attempt insertion rates were only 86%, whereas our success rate for i-gel was 91%. It is uncertain if this discrepancy could be attributed to heterogeneity in their investigators prior experience with the device or that it was just easier to insert the i-gel in our paralyzed patients.

In eighty anesthetized spontaneously breathing patients, Helmy *et al.*<sup>[10]</sup> found that the i-gel was associated with a higher OLP 25.6 (4.9) cm H<sub>2</sub>O and was significantly easier and faster to insert than the LMA classic, mean (SD) 15.6 (4.9) versus 26.2 (17.7) s. Their i-gel insertion time and OLP were comparable to our findings. On the contrary, Van Zundert and Brimacombe<sup>[11]</sup> found no difference in OLPs between the LMAS, LMA Proseal and i-gel during the spontaneous breathing phase in 150 patients. Insertion techniques vary amongst reported trials. As these authors used a laryngoscope and gastric tube-guided insertion technique, they found the LMAS easier and quicker to insert than the LMA-ProSeal and i-gel, with the LMAS having better anatomical positioning than the i-gel.<sup>[10]</sup>

Our study was not designed or powered to compare post-operative airway morbidity rates, but it was noteworthy that in our small series of 70 patients, three patients in the LMAS group had a mild sore throat and one patient had mucosal injury (as denoted by blood on the surface of airway upon removal). No post-operative complications were documented in the i-gel group. This could be attributed to the softer malleable material the i-gel is made of, whereas a fully deflated LMAS can still have relatively sharp edges that may abrade a patient's mucosa

upon repeated insertion. Other studies have reported transient lingual nerve injury in two females with both the LMAS (during lumbar discectomy) and i-gel (during ovum pick up). They presented with numbness at the tip of their tongues and had full spontaneous recovery 2 weeks post-operatively.<sup>[12]</sup>

In attempting to map out and gain exact information on the anatomical *in-situ* position of extraglottic airway devices, some investigators have used magnetic resonance imaging (MRI) to visualize the positions of the i-gel and the LMAS relative to skeletal and soft-tissue structures in volunteer subjects in a randomized, prospective, cross-over fashion. They found that the LMAS protruded deeper into the upper esophageal sphincter and reduced the area of the glottic aperture significantly more than the i-gel. The i-gel significantly compressed the tongue and although both devices displaced the hyoid bone ventrally, the i-gel did this to a greater degree. They concluded that the LMAS and i-gel differ significantly with regard to their spatial relationship with adjacent structures assessed by MRI, despite similar clinical and fiber optical findings. This could be relevant with regard to risk of aspiration, glottic narrowing and airway resistance and soft-tissue morbidity.<sup>[13]</sup>

The i-gel has some other reported advantages in an ambulatory surgical setting. In eye cases, insertion of the i-gel device provides better stability of intraocular pressure and the hemodynamic system compared with insertion of an endotracheal tube (ETT) or LMA in patients undergoing elective non-ophthalmic surgery.<sup>[14]</sup> In anesthetizing patients for MRI procedures (which is often done as a day case procedure), the i-gel is an ideal device as there are no artefacts with its use, compared with the artefacts with the LMA classic, unique and Supreme (even more pronounced with the LMA Proseal) related to ferromagnetic material in the pilot balloon valve.<sup>[15]</sup>

As the cuff volume of an air-filled airway device varies inversely with ambient pressure at altitude, this may result in problems with ventilation, aspiration and tissue ischemia in intubated patients transported by aircraft. It has been shown that cuff volumes of inflatable airway devices increased linearly with altitude when evaluated in an altitude chamber simulating ascent and descent from ground level to 15,000 feet (4572 m). This was most pronounced with the dual-cuffed supraglottic devices (Combitube, King tube) than the LMA, than the ETT, whereas the i-gel showed no volume change at any of the tested altitudes<sup>[16]</sup> making it a suitable airway device for medical evacuation procedures.

We acknowledge some of our study's limitations: (i) As in all airway studies, it is not possible to blind the airway device

to the user, this may introduce its own possible bias. (ii) Our recording of post-operative airway morbidity such as sore throat, dysphonia or dysphagia was conducted in the 1<sup>st</sup> h of the patient's anesthetic recovery period. The effects of residual anesthetic on board cannot be entirely discounted then, although we feel that any morbidity not detected in the first 45 min would have been reliably reported to us (had it occurred) by the nurses handling the discharge interview of patient from the ambulatory surgical center a few hours later. (iii) By virtue of the women's surgical center that this trial occurred in, our study population lacked males. This could affect the generalizability of our results *per se*. However, there are numerous other publications confirming efficacy of these extraglottic airways in males and children,<sup>[17-21]</sup> and those with difficult airways.<sup>[22]</sup>

We conclude that both the LMAS and the i-gel are equally effective extraglottic airway devices, offering similar OLPs, high insertion success rates at first attempt with similar ease and insertion times and both provided effective ventilation for laparoscopic female sterilizations in our study.

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